

APR - 3 2001



arplay medical

radiothérapie
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radioprotection

Premarket Notification [510(k)] Summary
Tab 4

December 22, 2000

Trade Name: Couch for Total Body RadiationCommon Name: Patient Support for Total Body Radiation TherapyClassification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Cîteaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: Mick Radio-Nuclear Inc., Total Body Irradiation Stand, K972709

Device Description: The Couch for Total Body Radiation consists of steel frame enclosed in aluminum sheeting. The wooden couch top is framed in aluminum and is raised and lowered on four endless screws by an electric motor actuated by the operator controlled buttons. The height of the table can be adjusted from 0.80 m (31.5 in) to 1.35 m (53.15 in).

The couch is rolled into treatment position on four wheels with locking brakes. The couch top is 0.60 m (23.6 in) wide by 2.0 m (78.7 in) long. The patient, up to 150 kg (330 lbs.), lies on the couch either supine for lateral treatments or on his/her side for AP/PA treatments. The radiation is given from the side on the table.

Two lateral Perspex sheets can be raised into position to scatter ("spoil") the radiation beam and creating a greater surface dose. The Perspex sheets are held in place by an aluminum bar with a locking knob.

Intended Use: The Couch for Total Body Radiation is intended for use in supporting a patient during total body external beam radiation therapy.

Technological Characteristics: See the attached predicate comparison table.

#	Feature	Total Body Irradiation Stand, K972709	Arplay Medical Couch for Total Body Radiation
1	Patient Orientation	Vertical, Whole Body	Horizontal, Whole Body
2	Patient Support	Stands on wood	Lies on wood
3	Additional Support	Seat, arm supports, hand grips	None necessary
4	Treatment Direction	AP/PA	AP/PA and/or Rt & Lt Lateral
5	Radiation Spoiler	Yes, Acrylic	Yes, Perspex
6	Maximum Patient Weight	Unknown	150 Kg (330 lbs.)
7	Use location	Rolls on floor	Rolls on floor
8	Vertical Motion	None	0.80 m (31.5 in) to 1.35 m (53.15 in)

The Arplay Medical Couch for Total Body Radiation has the same intended use as the predicate device. It is safer for infirm or unsteady patients because they are lying down.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR - 3 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard Borgi, M.D.
President and CEO
Arplay Medical S.A.
1 Route de Cîteaux
21110 Izeure
FRANCE

Re: K010063
Couch for Total Body Radiation
Dated: December 22, 2000
Received: January 8, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Dr. Borgi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Tab 3

Indications For Use

510(k) Number: K010063

Device Name: Couch for Total Body Radiation

Indications for Use:

Accessory to support a patient during total body external beam radiation therapy with or without the fold down beam scatterer.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ (per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

David A. Lippman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K010063